



AF IFW

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF APPEALS

Appellant:	Daniel E. ALES)	
Serial No:	09/783,967)	
Filed:	February 16, 2001)	
For:	SAFETY DEVICE FOR INTRAVENOUS INFUSION NEEDLES)	Appeal No.

APPELLANT'S REPLY BRIEF

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This is a reply to the response to arguments raised by the examiner in the Examiner's Answer dated October 4, 2004.

1. The examiner has clarified that designation 68 of Sweeney et al. U.S. patent 5,746,726 is the through passage "where the syringe luer (24) and needle (14) reside within the passage (68) of the body (52)". [Page 9 of the Examiner's Answer.]

This is exactly what Appellant has been saying all along, i.e., that through passage 68 of needle hub mount 52 is not a through passage where a needle is extended from one end and a flexible tubing from the other. As best shown in the cross section views of the Sweeney device as shown in Figs. 5 and 6, needle hub 22 is actually fitted into through passage 68. In other words, needle hub 22 is a conventional needle hub that is used with the conventional syringe 12. The essence of the Sweeney device is to fit onto needle hub 22 the mount 52 to which a shield 36 is hingedly attached. See Fig. 4. The fact that the needle 14 is in actuality a part of a conventional needle hub 22, and not a part of the passage 68, is amplified in

column 5, lines 13-24 where lines 13-16 state: "Mount 52 has an axial opening 68 therethrough that is sized and shaped to receive at least a portion of needle hub 22. Opening 68 includes provisions for retaining needle hub 22 in the mount." That the through passage and the needle hub to which the needle is attached are separate components is moreover clearly shown in the embodiment of Fig. 15 that shows needle hub 22a to be fitted to mount 52a through passage 68a. Thus, for the Sweeney embodiment upon which the examiner relied upon, the needle extends from the needle hub, not the through passage of the mount.

The embodiment of the Sweeney et al. device shown in Fig. 17 does disclose that the hub and the mount may be integrally formed as a unitary structure 80. Yet, even for this embodiment, Sweeney et al. continue to show, as do the other references Burns, U.S. patent 5,643,219 and Newby et al. U.S. patent 6,436,086, that the needle protective sheath is a component separate from the needle hub. This is because, prior to the instant invention, it has been the focus in the medical field that a needle protective housing should not obstruct the view of the phlebotomist to the tip of the needle, as she inserts the needle to the patient. This is important due to the fact that the bevel of a needle needs to be oriented at a particular angle relative to the skin the patient, in order for the needle to be readily and correctly inserted to the patient without causing the patient an inordinate amount of pain. Thus, in order to enable a phlebotomist to always have a clear view of the bevel of the needle, the needle protective housings, in most instances, are rotatably mounted to the needle, so that the protective housing may be rotated away from the line of sight of the phlebotomist as she lines up the needle to the vein of the patient.

Thus, prior to the instant invention, for the devices disclosed in both Sweeney et al. and Burns and also for the prior art intravenous devices, the accepted practice was to have the needle housing mounted to the needle hub by means of a collar, so that the needle sheath can be rotated away from the line of sight of the user. See for example column 3, lines 6-12 of Burns.

Therefore, as recognized by the examiner, each of the cited references discloses a needle sheath that is a separate component from the needle hub.

2. The integrally molding and integrating to the body of the needle protective housing for the instant invention device is neither an obvious modification nor a matter of design choice.

Indeed, Sweeney et al. recognize per their Fig. 17 embodiment that the needle hub may be integrated to the mount. Further, Sweeney et al. recognize that the needle point orientation is important and the needle point bevel may be oriented during the manufacturing process. See column 6, lines 43-47 of Sweeney et al. Yet even with the integrated needle hub/mount embodiment of Fig. 17, Sweeney et al nonetheless require that the needle protective sheath be a separate component that hingedly connects to the mount by means of the hinge holes 66. Therefore, it did not occur to Sweeney et al., certainly artisans in the field at issue, that the needle protection housing be made an integrated part of their device.

The same can be said with regard to the embodiment shown in Fig. 17 of Newby et al. There the needle shield 140a is connected to the IV needle hub 204 via collar 90a. Burns does teach injection molding. Yet Burns also teaches that injection molding is effected on separate components, which are put together to form his device.

Thus, there is no suggestion or motivation, let alone disclosure, in any of the references relied upon by the examiner that the needle sheath may be molded with the body of the device so that a unitary device be formed. Quite in contrast, each of those references specifically discloses that the needle sheath be a separate component from the needle hub, even when there is recognition that the bevel of a needle may be positioned in a given orientation during the manufacturing processes as shown in the Fig. 17 embodiment of Sweeney et al. Thus, the prior art in fact teaches away from the integration of the needle sheath to a body of an

intravenous device. If anything, the prior art confirms that the one piece intravenous device of the instant invention is not an obvious modification.

The instant invention is directed to an intravenous device that is quite different from a conventional syringe and/or a double ended needle used with a conventional Vacutainer or blood collection tube holder. Since an intravenous device, such as the butterfly wing device as disclosed in the specification, is a relatively small device, the addition of a needle protection housing would cause the device to be off balance, if the housing were to be mounted to the distal end of the device, as shown in the prior art. Thus, as shown in each of the figures of the specification of the instant invention, each of the needle protection housings, shown in Figs. 1, 3 and 6 for example, has to be configured to overly and embrace substantially the length of needle hub 8 of the intravenous device. By integrating the needle sheath directly to the needle hub as shown in Fig. 8 and claimed in the instant application, the additional weight which may otherwise cause unbalance for the intravenous device and difficulty for the user to insert the needle to a patient is removed. Thus, not only is the manufacturing process eased with the integrating of the needle sheath to the needle hub, the handling of the intravenous device as claimed is actually much easier than were the needle sheath mounted to the distal end of the needle hub, as was done in the prior art.

In view of the foregoing, appellant respectfully submits that the claimed invention is non-obvious over the prior art. Accordingly, Appellant respectfully requests that the rejections of the pending claims be reversed.

Respectfully submitted,



Louis Woo, Reg. No. 31,730
Law Offices of Louis Woo
717 North Fayette Street
Alexandria, VA 22314
Phone: (703) 299-4090

Date: Dec 2 2004